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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,270	03/17/2005	Stephen John Brough	06275-451US1	4129

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EXAMINER	
MOORE, SUSANNA	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,270	BROUGH ET AL.	
	Examiner	Art Unit	
	Susanna Moore	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-9 and 11-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-9 and 11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Substituted thiazolo[4,5-d]pyrimidin-2(3H)-one for the Treatment of ...". Please remove the word "Novel" from the title. The novelty of the invention is decided by the USPTO, not Applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "pharmaceutical agent" is vague. Agent for what? What are

these pharmaceutical agents? Are these preservatives? Maybe surfactants? What does Applicant intend? Is this supposed to cover all drugs?

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a chemokine mediated disease" is indefinite. The passage spanning line 6, page 5 to line 9, page 7 provides a list of unrelated conditions using open language "examples of such conditions". What other diseases are contemplated? It is unclear what diseases and treatments applicant is intending to encompass because there are so many different chemokines. It is possible that nearly all non-infectious diseases are mediated by chemokines of one sort or another. Hence, the claims are indefinite.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a disease in which angiogenesis is associated with raised CXCR2 chemokine levels" is indefinite. The passage spanning lines 1-4, page 7, recites, “Particular conditions which can be treated with the compound of the invention are rheumatoid arthritis, diseases in which angiogenesis is associated with raised CXCR2 chemokine levels, and COPD. The Specification does not provide a list such diseases. What are these diseases? It is unclear what diseases and treatments applicant is intending to encompass because there are so many different chemokines. Note that the claim also covers diseases, which themselves trigger changes in CXCR2 chemokine levels, e.g. CXCR2 change as effect rather than cause. Hence, the claims are indefinite.

Claims 3, 4, 6-8 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Such a utility cannot be deemed enabled.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(A) Breadth of claims.

(a) Scope of the compounds. The instant claims encompass one compound, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[2-hydoxy-((1-hydroxy)ethyl))ethyl]amino]thiazolo [4,5-d]pyrimidin-2(3 H)-one.

(b) Scope of the diseases covered. Claims 3, 4, 6-8 and 11-15 are drawn to a method of treating (**I**) a chemokine mediated disease, (**II**) inflammatory disease, (**III**) psoriasis, (**IV**)

COPD, (V) cancer, osteoporosis and a disease in which angiogenesis is associated with raised CXCR2 chemokine levels. Only the scope of the diseases (I-V) will be discussed below.

I. There are many chemokines and many receptors to which they bind. Below is a table which provides the many chemokines, the target cells and the specific receptor to which they bind, if known:

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Search&db=books&doptcmdl=GenBookHL&term=%22chemokines%22%5BAll+Fields%5D+AND+imm%5Bbook%5D+AND+126053%5Buid%5D&rid=imm.table.2501

Chemokines and their receptors.

Chemokine	Systematic name	Chromosome	Target cell	Specific receptor
†**ELR⁺CXC**	**CXCL**			
IL-8	8	4	Neutrophil, basophil, T cell	CXCR1, 2
GROα	1	4	Neutrophil	CXCR2 >> 1
GROβ	2	4	Neutrophil	CXCR2
GROγ	3	4	Neutrophil	CXCR2
ENA-78	5	4	Neutrophil	CXCR2
LDGF-PBP	7	4	Fibroblast, neutrophil	CXCR2
GCP-2	6	4	Neutrophil	CXCR2
†**ELR⁻CXC**				

PF4	4	4	Fibroblast	Unknown
Mig	9	4	Activated T cell	CXCR3
IP-10	10	4	Activated T cell ($T_H1 > T_H2$)	CXCR3
SDF-1α/β	12	10	$CD34^+$ bone marrow cell, T cell, dendritic cell, B cell, naive B cell, activated CD4 T cell	CXCR4
BUNZO/STRC33	16	17	T cell, NK T cell	CXCR6
I-TAC	11	4	Activated T cell	CXCR3
BLC/BCA-1	13	4	Naive B cells, activated CD4 T cells	CXCR5

CC	**CCL**			
MIP-1α	3	17	Monocyte/macrophage, T cell ($T_H1 > T_H2$), NK cell, basophil, immature dendritic cell, bone marrow cell	CCR1, 5
MIP-1β	4	17	Monocyte/macrophage, T cell ($T_H1 > T_H2$), NK cell, basophil, immature dendritic cell, bone marrow cell	CCR1, 5
MDC	22	16	Immature dendritic cell, IA NK cell, T cell ($T_H2 > T_H1$), thymocyte	CCR4
TECK	25	19	Macrophage, thymocytes, dendritic cell	CCR9
TARC	17	16	T-cell ($T_H2 > T_H1$), immature dendritic cell, IA NK cell, T cell ($T_H2 > T_H1$), thymocyte	CCR4
RANTES	5	17	Monocyte/macrophage, T cell (memory T cell > T cell; $T_H1 > T_H2$), NK cell, basophil, eosinophil, dendritic cell	CCR1, 3, 5
HCC-1	14	17	Monocyte	CCR1
HCC-4	16	17	Monocyte	CCR1
DC-CK1	18	17	Naive T cell > T cell	Unknown
MIP-3α	20	2	T cell (memory T cell > T cell), peripheral blood mononuclear cell, bone marrow cell-dendritic cell	CCR6
MIP-3β	19	9	Naive T cell, mature dendritic cell, B cell	CCR7
MCP-1	2	17	T cell, monocyte, basophil	CCR2

MCP-2	8	17	T cell, monocyte, eosinophil, basophil	CCR2
MCP-3	7	17	T cell, monocyte, eosinophil, basophil, dendritic cell	CCR2
MCP-4	13	17	T cell, monocyte, eosinophil, basophil, dendritic cell	CCR2, 3
None	12	(11)	Eosinophil, monocyte, T cell	CCR2
Eotaxin	11	17	Eosinophil	CCR3
Eotaxin-2/MPIF-2	24	?	T cell (?), eosinophil, basophil	CCR3
I-309	1	17	Neutrophil (TCA-3 only), T cell	CCR8
MIP-5/HCC-2	15	17	T cell, monocyte, neutrophil (?), dendritic cell	CCR1, 3
MPIF-1	23	17 (?)	Monocyte, T cell (resting), neutrophil (?)	Unknown
6Ckine	21	9	Naive T cell, B cell, mesangial cells (?)	CCR7
CTACK	27	9	T cell	CCR10
MEC	28	5	T cell, eosinophil	CCR10, 3
C and CX3C				
Lymphotactin	XCL 1	1 (1)	T cell, NK cell	XCR1
Fractalkine	CX3CL 1	16	T cell, monocyte, neutrophil (?)	CX3CR1

ELR refers to the three amino acids that precede the first cysteine residue of the CXC motif. If these amino acids are Glu-Leu-Arg (ie ELR^+), then the chemokine is chemotactic for neutrophils while if they are not (ELR^-) then the chemokine is chemotactic for lymphocytes.

It may well be that a significant percentage of all cellular-based disorders are associated with a chemokines.

II. An inflammatory disease can be defined as a disease characterized by inflammation anywhere in the body. This includes allergic rhinitis, inflammatory bowel disease,

irritable bowel syndrome, asthma and osteoarthritis. Inflammation is the body's first response to injury, e.g. trauma, infection irritation, etc. This is a non-specific immune response. Inflammation has two main components - cellular and exudative.

The exudative component involves the movement of fluid, usually containing many important proteins such as fibrin and immunoglobulins (antibodies). Fibrinogen is important for clot formation and the prevention of further loss of blood. Immunoglobulins may act as specific or nonspecific *opsonins* facilitating thus the process of phagocytosis, or may participate in antibody-dependent cell-mediated cytotoxicity (ADCC) by which target cells are destroyed by killer cells. Blood vessels are dilated upstream of an infection (causing redness and heat) and constricted downstream while capillary permeability to the affected tissue is increased, resulting in a net loss of blood plasma into the tissue - giving rise to edema or swelling. The swelling distends the tissues, compresses nerve endings, and thus causes pain.

The cellular component involves the movement of white blood cells from blood vessels into the inflamed tissue. Professional phagocytes (neutrophils, eosinophils, monocytes and tissue macrophages) are essential performing phagocytosis, lymphocytes are involved in the specific immune responses, endothelial cell in the regulation of leukocyte emigration from the blood into inflamed tissue and platelets with mast cells in the production of early phase mediators.

Some examples of inflammatory diseases are as followed, but not limited to: allergies, appendicitis, arteritis, arthritis, asthma, blepharitis, bronchiolitis, bronchitis, bursitis, cervicitis, cholangitis, cholecystitis, chorioamnionitis, colitis, conjunctivitis, cystitis, dacryoadenitis, dermatitis, dermatomyositis, encephalitis, endocarditis, endometritis, enteritis, enterocolitis, epicondylitis, epididymitis, fasciitis, fibrositis, gastritis, gastroenteritis, gingivitis, hepatitis,

hidradentitis supparativa, ileitis, immune reconstitution inflammatory syndrome (IRIS), laryngitis, mastitis, meningitis, myelitis, myocarditis, myositis, nephritis, omphalitis, oophoritis, orchitis, osteitis, otitis, pancreatitis, parotitis, pelvic inflammatory disease (PID), pericarditis, peritonitis, pharynx, pleuritis, phlebitis, pneumonitis, protitis, prostatitis, rhinitis, salpingitis, sinusitis, stomatitis, synovitis, tendonitis, tonsillitis, uveitis, vaginitis, vasculitis and vulvitis.

These are all different diseases in different parts of the body, which require different treatment, e.g. an appendicitis requires the removal of the appendix, while a pelvic inflammatory disease requires treatment with an antibiotic or hepatitis requires treatment with an antiviral agent.

Another issue which needs to be addressed is "or at risk of" which is prevention, for which enablement has not been established. Also, everyone is at risk for inflammatory diseases, so this embraces giving the drug to healthy people.

III. Psoriasis is a hyperproliferative group of skin diseases of the immune system. According to the National Psoriasis Foundation, there are five types of psoriasis: plaque, guttate, inverse, pustular and erythrodermic. There are treatments to help control the symptoms but not to treat the disease. Rheumatoid arthritis is also an autoimmune disease for which there is no treatment, only the symptoms of the disease can be treated.

IV. Chronic Obstructive Pulmonary Disease (COPD) is a slowly progressive disease of the airways that is characterized by a gradual loss of lung function. COPD includes chronic obstructive Bronchitis (which involves inflammation and eventual scarring of the

bronchi) and emphysema (enlargement and destruction of the alveoli). Emphysema comes in several forms, including Congenital Lobar Emphysema, Bullous Emphysema, Centrilobular Emphysema (Proximal acinar emphysema), Panacinar (panlobular), Distal acinar (paraseptal) as well as Alpha-1 antitrypsin (AAT) deficiency, which is the genetic form of emphysema; patients often have both a form of bronchitis and emphysema. Ordinary chronic bronchitis is sometimes included with COPD even if there is no actual obstruction, and asthmatic bronchitis is generally included in COPD as well. Persons with COPD typically develop smaller air passageways, which can become clogged with mucus and have partially destroyed alveoli. There is no pharmaceutical treatment for COPD per se. Instead, treatment is supportive and designed to relieve symptoms and improve quality of life. Thus, oxygen is often given to partially compensate for the loss of lung function. Bronchodilators can expand passageways in the lungs, Corticosteroids can reduce inflammation and Antibiotics can ward off bacterial infections, but none of these treat the COPD itself.

(V) Cancers are classified by the type of cell that resembles the tumor and, therefore, the tissue presumed to be the origin of the tumor. The following general categories are usually accepted:

- Carcinoma: malignant tumors derived from epithelial cells.
- Lymphoma and Leukemia: malignant tumors derived from blood and bone marrow cells
- Sarcoma: malignant tumors derived from connective tissue, or mesenchymal cells.
- Mesothelioma: tumors derived from the mesothelial cells lining the peritoneum and the pleura.
- Glioma: tumors derived from glia, the most common type of brain cell.

- germ cell tumours: tumors derived from germ cells, normally found in the testicle and ovary.
- Choriocarcinoma: malignant tumors derived from the placenta.

Cancers include the following, but are not limited to: (topography) eye, endometrium, bladder, breast, colon, penis, kidney, liver, lung, brain, small cell lung cancer, esophogus, gall bladder, ovary, pancreas, stomach, cervix, colon/rectum, mouth, larynx, head/neck, thyroid, prostate, testicle, skin, squamous cell carcinoma, anus and leukemia; (cell type/morphology) acute lymphocytic leukemia, acute lymphoblastic leukemia, B-cell lymphoma, T-cell lymphoma, Hodgkins lymphoma, non-Hodgkins lymphoma, hairy cell lymphoma, Burgett's lymphoma, acute myelogenous leukemia, chronic myelogenous leukemia, myelodyplastic syndrome, promyelocytic leukemia, fibrosarcoma, rhabdomyosarcoma, astrocytoma, neuroblastoma, glioma, schwannomas, melanoma, seminoma, teratocarcinoma, osteosarcoma, xenoderoma pigmentosum, keratoctanthoma, thyroid follicular cancer, Kaposi's sarcoma, angiosarcoma, dermatofibrosarcoma, desmoid tumor, desmoplastic small round cell tumor, extraskeletal chondrosarcoma, extraskeletal osteosarcoma, hemangiopericytoma, hemangiosarcoma, leiomyosarcoma, liposarcoma, lymphangiosarcoma, malignant fibrous histiocytoma, neurofibrosarcoma, synovial sarcoma, Askin's Tumor, Ewing's sarcoma and alignant hemangioendothelioma.

(B) The nature of the invention and predictability in the art: The invention is directed toward medicine and is therefore physiological in nature. It is well established that "the scope of

enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(C) Direction or Guidance: That provided is very limited. The dosage range information, found on page 8 of the Specification gives concentrations for the compositions 0.01-50 %wt of active ingredient, which is very broad. There is no daily dosage information in the Specification. Thus, there is no specific direction or guidance regarding a regimen or dosage effective specifically for any and all diseases listed in the Scope of diseases above.

(D) State of the Prior Art: These compounds are substituted thiazolo[4,5-d]pyrimidine . So far as the examiner is aware, no substituted thiazolo[4,5-d]pyrimidine of any kind have been used for treating any and all diseases listed in the Scope of Diseases.

(E) Working Examples: The invention is drawn to a method of treating all the diseases found in the Scope of diseases. There are no working examples or even animal models, in the Specificaiton drawn to this utility to support the use of substituted thiazolo[4,5-d]pyrimidine to treat any and all diseases listed in the Scope of diseases above. On pages 16-17 of the Specification an IL-8 inhibition and a GROα calcium mobilization assay is presented with very little data to support the said utility. No data is present for treatment of all inflammatory diseases, psoriasis or COPD, either directly or in the form of animal models. No evidence presented that all the diseases and disorders listed in the Scope of diseases are mediated by either IL-8 or

GROα.

(F) Skill of those in the art: The diseases and disorders listed above cannot be treated by any one drug. These are all different diseases and disorders, which occur at different locations and by different modes of action in the body. Rheumatoid arthritis, an inflammatory disease, itself can be treated only with compounds or drugs that directly suppress alpha tumor necrosis factor (TNF), e.g. Enbrel, Humira and Remicade. Applicants compounds are not disclosed to block alpha TNF, let alone is their evidence that they do. The skill of one in the art is such that only such agents have been made to work.

There are two in vitro assays found in the Specification on pages 16-17 but no evidence of any correlation between the assays and human diseases. Trivedi et. al. (Ann. Reports Med. Chem.; 2000, 35; 191-200) recites in the third paragraph, page 193, "[t]he exact role of IL-8 in human disease is yet to be determined." Thus, the potential of using IL-8 or its receptors to treat any disease remains at the level of speculation.

Skill of the art: The prior art knows that there never has been a compound capable of treating cancer generally. "The cancer therapy art remains highly unpredictable, and no example exists for efficacy of a single product against tumors generally." (<http://www.uspto.gov/web/offices/pac/dapp/1pecba.htm#7 <http://www.uspto.gov/web/offices/pac/dapp/1pecba.htm>> ENABLEMENT DECISION TREE, Example F, situation 1) There are compounds that treat a modest range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary

to our present understanding in oncology.

(G) The quantity of experimentation needed: Owing especially to factors A, C, E and F, the amount of experimentation is expected to be high.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claims 1, 3, 4, 6-9 and 11-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to solvates. But the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the

'881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Double Patenting

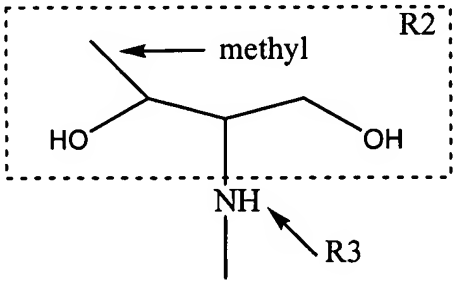
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

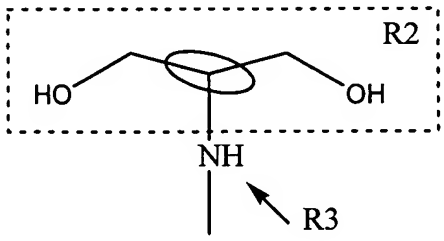
with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 6-9 and 11-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,790,850. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 4, column 39, lines 54-56, of the referenced patent, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, is a structural homolog of the compound found in claim 1 of the instant application. The only difference between these compounds is the substitution at R2, the R2 substituent has a hydrogen versus Applicants methyl group, which is illustrated with the structures below. Thus, the compounds are not patentably distinct.



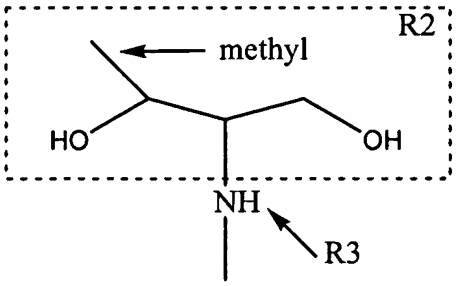
R2 and R3 with attached nitrogen of the current case



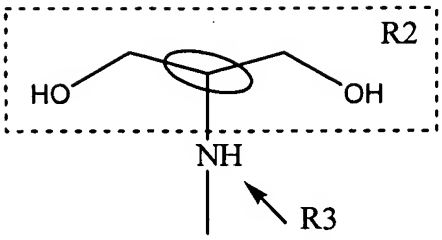
R2 and R3 with the attached nitrogen of the co-pending case

Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Claims 1, 3, 6-9, 11, 13, 14 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 10, 11 and 14-19 of copending Application No. 10/863995. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound in claim 4, the last specie listed at the bottom of the page, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-l-(hydroxymethyl))ethyl]amino]thiazolo [4,5-d]pyrimidin-2(3 H)-one is a homolog of the compound in instant claim 1, formula (I), 5-[[(2,3-difluorophenyl)methyl]thio]-7-[l,1-(di(hydroxymethyl))ethyl]amino]thiazolo [4,5-d]pyrimidin-2(3 H)-one. The only difference between these compounds is a hydrogen versus Applicants methyl group, which is illustrated below. The same argument used above addresses this scenario.



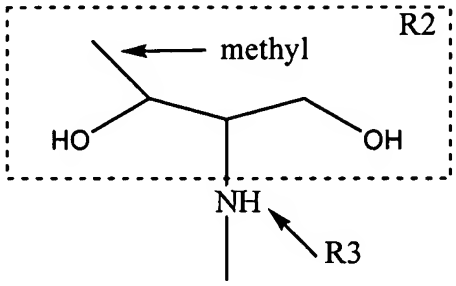
R2 and R3 with attached nitrogen of the current case



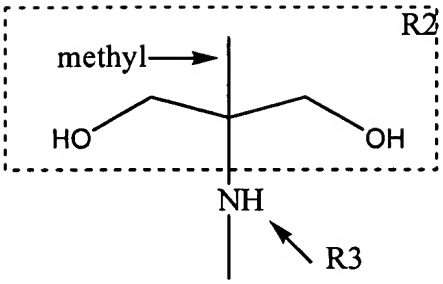
R2 and R3 with the attached nitrogen of the co-pending case

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10528316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 1 of formula (I) of the co-pending application, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[l,1-(di(hydroxymethyl))ethyl]amino]thiazolo [4,5-d]pyrimidin-2(3 H)-one, is a positional isomer of the specie found in claim 1 of the instant application. The difference between the two compounds is the location of the methyl group illustrated below. The same homology/positional isomer argument used above applies here.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SM

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Mark L. Berch
Primary examiner
Art Unit 1624
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